DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 8, 2014

BioCare Asia Corporation Ltd.
c/o Dr. Ke-Min Jen
Official Correspondent
No. 260, Mayun Road
New District
Suzhou, Jiangsu, 215129 P.R.C.

Re: K141924
Trade/Device Name: HD Blood Pressure Monitor, Upper Arm Type: 3161
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 5, 2014
Received: July 16, 2014

Dear Dr. Ke-Min Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

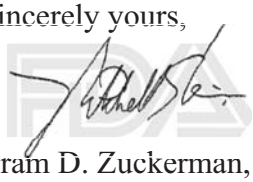
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): __K141924_____

Device Name: __ HD Blood Pressure Monitor, Upper Arm Type: 3161____

Indications For Use: HD 3161 Blood Pressure Monitor is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. This system should only be used for the testing on people over 18 years of age and over.

This device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated. The cuff circumference is limited to be 9.44 to 16.9 inches (24cm～43cm).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR **Over-The-Counter Use** __X__
(Per 21 CFR 801.109)

Summary of Safety and Effectiveness

(According to 21 CFR 807.92)

510(k) Summary for ___K141924____

Submitter's information

Name : BioCare Asia Corporation Ltd.

Address : No.260, Mayun Road, New District, Suzhou, Jiangsu, 215129, P.R.C.

Phone number : +86 (512) 6809-1772

Fax number : +86 (512) 6809-7761

Representative person : Albert Chen / Administrator

FDA Registration : ＃3003979308

510k Contact person : Dr. Jen, Ke-Min

Tel: +886-3-5208829 Fax:+886-3-5209783

Email: ceirs.jen@msa.hinet.net

Date of preparation: July 1, 2014

Device name

Trade name : BioCare Asia HD 3161 Blood Pressure Monitor

Device name : HD Blood Pressure Monitor, Upper Arm Type: 3161

Common name : Blood Pressure Monitor

Classification

Classification name : Non-Invasive Blood Pressure Monitoring System

Regulation number : 21CFR Section 870.1130

Class : II (Two) performance standards

Specialty : Cardiovascular

Product code : DXN

Predicate devices

U-RIGHT TD-3127 Blood Pressure Monitoring System (K100658)
TaiDoc Technology Corporation

Device Information

Device description: HD 3161 Blood Pressure Monitor measures both systolic and diastolic blood pressure and heart pulse rate via a standard oscillometric method. The oscillometric method senses the vibrating signal via the closed air pipe system and utilizes a microcomputer to automatically sense the characteristics of the pulse signal. Unlike with the traditional measuring method, based on the Korotkov sound, with the oscillometric method the use of a stethoscope is not required. Through simple calculations, this method provides accurate blood pressure readings: the systolic pressure is defined as the blood pressure when the cuff pressure oscillating amplitude begins to increase, while the diastolic blood pressure is defined as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Indication for use: HD 3161 Blood Pressure Monitor is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. This system should only be used for the testing on people over 18 years of age and over.

This device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated. The cuff circumference is limited to be 9.44 to 16.9 inches (24cm～43cm).

Test Summary:

1. ELECTRIC SAFETY, EMC and Biocompatibility test reports,

General safety	IEC 60601-1:2005	PASS
	IEC 60601-1-11:2010	PASS
	EN 1060-1:2002, EN 1060-3:2005	PASS
EMC conformity	IEC 60601-1-2: 2007	PASS
Biocompatibility	ISO 10993-5:2009	PASS
	ISO 10993-10:2010	PASS
FCC 47 CFR Part 18	ANSI C63.4: 2009	PASS

2. PERFORMANCE & CLINICAL TEST

IEC 80601-2-30:2013

AAMI / ANSI / ISO 81060-2:2013

Comparison with predicate device and conclusion

Similarities:

Comparison item	Proposed device	Predicate device
Applicant	BioCare Asia Corporation Ltd.	TaiDoc Technology Corporation
Trade name	BioCare Asia HD 3161 Blood Pressure Monitor	U-RIGHT TD-3127 Blood Pressure Monitoring System
Model name	HD 3161	TD-3127
510K number	New listing	K100658
Technological characteristics	Oscillometric method	Oscillometric method
Measuring method	Oscillometric method, automatic inflation and measurement	Oscillometric method, automatic inflation and measurement
Sensor	Semiconductor gauge sensor	Semiconductor gauge sensor
Rapid air release	By an active electronic control valve	By an active electronic control valve
System anatomical sites	Upper arm	Upper arm
Display and user interaction	LCD monitor	LCD monitor
Power source	Batteries or AC adapter	Batteries or AC adapter
Measurement range	Systolic 50 – 250 mmHg Diastolic 30 – 180 mmHg Pulse 40 – 199 beats per minute	Systolic 50 – 250 mmHg Diastolic 30 – 180 mmHg Pulse 40 – 199 beats per minute
Pressure accuracy	Pressure: ±3mmHg or ±2% of readout value	Pressure: ±3mmHg or ±2% of readout value
Pulse accuracy	±4% of reading value	±4% of reading value
Operating temperature and humidity	Temperature: 32~104°F (0~40℃) RH:15% to 90%	Temperature: 32~104°F (0~40℃) RH:15% to 90%
Storage temperature and humidity	Temperature: 23~122°F (-5~50℃) RH:15% to 95%	Temperature: 23~122°F (-5~50℃) RH:15% to 95%
Cuff material	Cuff: nylon (PVC bladder, non-latex) Biocompatibility: ISO 10993-5:2009, ISO 10993-10:2010	Cuff: nylon (PVC bladder, non-latex) Biocompatibility: ISO 10993-5:2009, ISO 10993-10:2010

Differences:

Comparison item	Proposed device	Predicate device
Dimensions (L*W*H) mm	134.8(L)x94.6(W)x31.5(H) mm	150(L) × 96(W) × 66(H)mm
Weight	425g (w batteries)	250g
Memory	2 * 90 measurements	100 measurements
Auto shutoff	90 sec after last key operation	180 sec after last key operation

Summary with predicate device and conclusion

The new device, HD 3161 Blood Pressure Monitor is substantially equivalent to the U-RIGHT TD-3127 Blood Pressure Monitoring System (K100658) and they are the same upper arm type of the blood pressure monitor.

The intended use and the indications for use of the HD 3161 Blood Pressure Monitor as described in its labeling are the same as the predicate device and the two devices are intended to be used in the same measurement range; in addition, there are the same operating and storage environments.

The HD 3161 Blood Pressure Monitor and the predicate devices are substantially equivalent in all of the technological characteristics of patient contact materials, performance, biocompatibility function, mechanical safety, standards met, electrical safety, and EMC.

The main differences for the two devices are overall dimensions, including dimensions, weight, memory, and the time of auto shutoff. The overall appearance differences are not safety aspect. Thus the new device is substantially equivalent to the predicate devices in this aspect.

BioCare Asia Corporation Ltd. believes this information and the referred documentation to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.